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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,291	03/13/2006	Rodney William Kelly	20747/280	8533

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,291	KELLY, RODNEY WILLIAM	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-14,16,20-45,47-49,51,66,67,69,73-75 and 78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10,12-14,16,20-45,47-49,51,66,67,69,73-75 and 78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application is a 371 of PCT/GB04/01572. For applications filed under 371, PCT rules for lack of unity apply.

Claims 1-10, 12-14, 16, 20-45, 47-49, 51, 66-67, 69, 73-75, 78, are pending and under consideration by the Examiner.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2, 5-6, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a prostaglandin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 2, claims 1-2, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a β-adrenergic blocker which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 3, claims 1-2, 3, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a blocker of cAMP export from the cell which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 4, claims 1-2, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient forskolin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 5, claims 1-2, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a cAMP phosphodiesterase inhibitor which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 6, claims 1-2, 4, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a cAMP analogue which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 7, claims 1-2, 5-6, 7-10, 12-14, 16, 20-22, 23-26, drawn to a method of inducing tolerance to an antigen in a patient, the method comprising administering to the patient a cholera

toxin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 8, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient a prostaglandin or agonist thereof which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 9, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient a β-adrenergic blocker which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 10, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient a blocker of cAMP export which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 11, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient forskolin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 12, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient a cAMP phosphodiesterase inhibitor which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 13, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient a cAMP analogue which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 14, claims 27-30, drawn to a method of treating autoimmune disease, the method comprising administering to the patient cholera toxin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 15, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient a prostaglandin or agonist thereof which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 16, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient a β-adrenergic blocker which raises the effective cAMP

concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 17, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient a blocker of cAMP export which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 18, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient forskolin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 19, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient a cAMP phosphodiesterase inhibitor which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 20, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient a cAMP analogue which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 21, claims 31-35, drawn to a method of treating an allergic disease, the method comprising administering to the patient cholera toxin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 22, claims 36-37, 40-45, 47-49, 51, drawn to a composition comprising prostaglandin or agonist thereof which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 23, claims 36-37, 42-45, 47-49, 51, drawn to a composition comprising a β-adrenergic blocker which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 24, claims 36-37, 38, 42-45, 47-49, 51, drawn to a composition comprising a blocker of cAMP export which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 25, claims 36-37, 42-45, 47-49, 51, drawn to a composition comprising forskolin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 26, claims 36-37, 42-45, 47-49, 51, drawn to a composition comprising a cAMP phosphodiesterase inhibitor which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 27, claims 36-37, 42-45, 47-49, 51, drawn to a composition comprising a cAMP analogue which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 28, claims 36-37, 42-45, 47-49, 51, drawn to a composition comprising cholera toxin which raises the effective cAMP concentration in a monocyte cell and granulocyte-macrophage colony stimulating factor (GMCSF).

Group 29, claims 66-67, 69, drawn to a therapeutic system for inducing tolerance to an antigen in a patient, the system comprising an agent which raises the effective cAMP concentration in a monocyte cell and GMCSF or a derivative thereof.

Group 30, claim 73, drawn to a method of stimulating or enhancing granulysin expression in cells of a macrophage/monocyte lineage comprising administering to the cells a therapeutic system comprising an agent which raises the effective cAMP concentration in a monocyte cell and GMCSF or a derivative thereof.

Group 31, claim 74-75, drawn to a method of treating a viral infection in a patient comprising administering to the patient a therapeutic system comprising an agent which raises the effective cAMP concentration in a monocyte cell and GMCSF or a derivative thereof.

Group 32, claim 78, a method of stimulating or enhancing IL-10 expression in, and secretion from, cells of the a macrophage/monocyte lineage comprising administering to the cells a therapeutic system comprising an agent which raises the effective cAMP concentration in a monocyte cell and GMCSF or a derivative thereof.

The inventions listed as Groups I-32 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The PCT rules define a special technical feature as a feature, which defines a contribution over the prior art. The first claimed invention fails to recite such a feature, since Piquet-Pellorce et al (1991) teach a method of administering prostaglandin E2 and G-MCF (see pages 2377-2382 and abstract). Since the first claimed invention lacks a special technical feature, the other claimed inventions cannot share a special technical feature with the first claimed invention. The inventions of Groups 1-21 are patentably distinct from the products of Groups 22-28 because the products of Groups 22-28 can be used in other methods such as immunoassays or immunoaffinity chromatography. The methods of Groups 1-21 and 29-32 are patentably distinct from each other because each recites method steps not required by the other, comprise treating different conditions, each method uses different patient populations as starting materials and the search of all methods in one patent application would result in an undue search burden.

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If Applicant elects the invention of any one of Group I, 8, 15, or 22, Applicant must elect one species of prostaglandin as recited, for example in claim 6.

If Applicant elects the invention of any one of Group 6, 13, 20, or 27, Applicant must elect one species of cAMP analogue as recited, for example in claim 4.

If Applicant elects the invention of any one of Group 5, 12, 19, or 26, Applicant must elect one species of PDE inhibitor as recited, for example in claims 12-14.

If Applicant elects the invention of any one of Groups 8-14, Applicant must elect one species of autoimmune disease as recited in claim 28 and antigen for the specific autoimmune disease as recited in claim 30.

If Applicant elects the invention of any one of Groups 1-7, Applicant must elect one species of administration as recited, for example in claim 16.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-4, 6, 12-14, 16, 21, 28, 30, 39, 41, 47-49, 69, recite the species.

The following claim(s) are generic: 1, 5, 7-10, 20, 22, 23-27, 29, 31-37, 40, 42-45, 51, 66-67, 73-75, 78.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the prostaglandins, cAMP analogues, and PDE inhibitors are structurally and functionally distinct chemical compounds and therefore cannot constitute a unifying technical feature, while each of the autoimmune diseases and methods of administration are distinct and therefore cannot constitute a unifying technical feature.

Rejoinder under *In re Ochiai* and *In re Brouwer*

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646